

U.S. NUCLEAR REGULATORY COMMISSION OBSERVATION AUDIT REPORT OAR-06-02,
OBSERVATION AUDIT OF THE U.S. DEPARTMENT OF ENERGY, OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT, OFFICE OF QUALITY ASSURANCE, AUDIT
OQA-BSC-06-02 OF BECHTEL SAIC COMPANY, LLC, CORRECTIVE ACTION PROGRAM

/RA/ 1/18/06

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1.0 INTRODUCTION

On December 12–22, 2005, staff from the U.S. Nuclear Regulatory Commission (NRC), Division of High-Level Waste Repository Safety, and the Center for Nuclear Waste Regulatory Analyses (CNWRA) observed the U.S. Department of Energy (DOE), Office of Civilian Radioactive Waste Management (OCRWM), Office of Quality Assurance (OQA), audit OQA–BSC–06–02 of Bechtel SAIC Company, LLC (BSC). The OQA team audited the BSC Corrective Action Program (CAP) at the BSC facilities in Las Vegas, Nevada. The November 7, 2005, Audit Plan states that the scope of this audit was to evaluate (1) the adequacy, implementation, and effectiveness of the CAP, (2) the implementation of the revised procedure QA–PRO–1002, Trend Evaluation and Reporting, and (3) actions initiated to resolve open conditions adverse to quality in the trend area. Performing these three evaluations would allow the audit team to determine the effectiveness of the overall corrective action process. The NRC observers assessed the effectiveness of the audit team and the audit process.

2.0 MANAGEMENT SUMMARY

DOE conducted an audit of the BSC CAP through evaluations of procedures for compliance with QA program requirements and a selection of Condition Reports (CRs) initiated since the previous CAP audit conducted in January 2005 (OCRWMP–OQA–05–02) to determine the effectiveness of the corrective action process.

During the conduct of the audit, the observers noted that the audit team was not evaluating the implementation of the Trend Evaluation and Reporting procedure and did not appear to be performing the actions necessary to determine the effectiveness of the corrective action process. After comments from the observers, the audit team evaluated the Trend Program, resulting in a recommendation that the classification of an open Condition Report (CR–6711) be elevated from Level B to Level A. The audit team also added evaluations of corrective action effectiveness reviews that had not originally been included in the audit scope.

The audit team identified one minor adverse condition relating to procedures and four minor adverse conditions relating to procedure implementation. The audit team identified four opportunities for improvement. The audit team concluded that the Corrective Action Program (less trending) was adequate, the Trend Program was unsatisfactory, and the overall corrective action process was ineffective. The observers determined that the audit team performed effectively and met the scope of the audit after they included the evaluation of the Trend Program in the audit activities. The observers agreed with the audit team's conclusions and findings.

3.0 AUDIT PARTICIPANTS

DOE Audit Team Members

William Glasser, Navarro Quality Services (NQS), Audit Team Leader

John Doyle, NQS, Auditor

Donald Harris, NQS, Auditor

James Voight, NQS, Auditor

Observers

Thomas Matula, NRC, Observation Team Leader

Robert Brient, CNWRA, QA Specialist

4.0 REVIEW OF THE AUDIT AND AUDITED ORGANIZATION

The auditors conducted the audit in accordance with Line Procedure (LP)–18.3Q–OCRWM, Quality Assurance Internal Audit Program. The auditors reported conditions adverse to quality in accordance with Administrative Procedure (AP)–16.1Q, Condition Reporting and Resolution. The observers followed NRC Manual Chapter 2410, Conduct of Observation Audits, while observing the audit.

4.1 Scope of the Audit

The November 7, 2005, Audit Plan, states that the scope of this audit was to evaluate (1) the adequacy, implementation, and effectiveness of the Corrective Action Program, (2) the implementation of the revised procedure QA–PRO–1002, Trend Evaluation and Reporting, and (3) actions initiated to resolve open conditions adverse to quality in the trend area. Performing these three evaluations would allow the audit team to determine the effectiveness of the overall corrective action process.

The auditors evaluated the adequacy, implementation, and effectiveness of applicable requirements and activities relating to the CAP, which addresses QA program requirements for (1) nonconforming materials, parts, and components and (2) corrective action. The auditors evaluated the activities in relation to: (1) the latest applicable revisions of DOE/RW–0333P, Quality Assurance Requirements and Description (QARD); and (2) the administrative procedures AP–16.1Q, Condition Reporting and Resolution, and AP–16.4Q, Causal Analysis and Corrective Action Plan Development. The audit team also examined corrective actions for CRs identified from the January 2005 audit of the CAP.

During the conduct of the audit, the observers noted that the audit team was not evaluating the implementation of the Trend Evaluation and Reporting procedure and did not appear to be performing the actions necessary to determine the effectiveness of the corrective action process. After comments from the observers, the audit team evaluated the Trend Program and added evaluations of corrective action effectiveness reviews that had not originally been included in the audit scope.

4.2 Conduct and Timing of the Audit

The observers determined that the audit team performed the audit effectively and demonstrated sound knowledge of the applicable implementing procedures and QA program requirements. The audit team members conducted thorough interviews, challenged and questioned responses when appropriate, and effectively employed their checklists. The auditors caucused each afternoon with the observers to discuss the current audit status and potential issues. The auditors, BSC management, and observers met periodically to discuss the audit status and any new and developing issues.

The timing of the audit was appropriate in relation to ongoing corrective actions and in relation to the previous audit of the CAP. The Audit Team Leader appropriately included the evaluation of ongoing corrective actions relating to the Trend Program and corrective action effectiveness reviews so that the audit team could make a conclusion regarding the effectiveness of the overall corrective action process. Although the audit checklist did not cover the segment of AP–16.1Q relating to effectiveness reviews of corrective actions to preclude recurrence, the auditors reviewed the few affected CRs after observers commented on this omission.

4.3 Audit Team Qualifications and Independence

The observers reviewed the qualifications for the Audit Team Leader and auditors and verified their qualifications and their independence of the areas reviewed. All audit team members held lead auditor certifications.

4.4 Examination of Quality Assurance Elements

The audit team conducted evaluations of both the adequacy of CAP procedures and the implementation of the CAP. In evaluating CAP procedure implementation, the audit team reviewed a sample of CRs to determine the adequacy or appropriateness of

- CR descriptions
- CR classification (i.e., level assignment)
- Extent of condition documentation
- Cause analysis
- Corrective action plans
- Completed corrective actions
- CR records

The audit team determined that the CAP procedures adequately addressed QARD requirement and that the implementation of individual performance elements of the CAP was adequate.

The audit team focused their evaluations on CRs issued since the January 2005 audit of the CAP comprising 6 Level A, 111 Level B, and approximately 700 Level C CRs. The CAP classifies CRs as

- Level A – Significant Adverse Condition (as defined in 10 CFR § 63.142)
- Level B – Adverse Condition
- Level C – Minor Adverse Condition

The audit team reviewed CRs issued as a result of the January 2005 CAP audit and determined that the Level B CR–4866, regarding inadequate or missing extent of condition analyses, was still open pending completion of corrective actions and verification.

As a result of reviewing the Trend Program, the audit team determined the Trend Program

- Is not handled as a priority for management attention,
- Is performed at an intermediate line organization level, and
- Has historically identified broad causal issues with no adverse trends.

Likewise, audit OCRWMC–OQA–05–19 (September 2005) resulted in a Level B CR–6711 which indicated that the Trend Program had not identified actual adverse trends in requirements management.

The audit team concluded that the CAP (regarding the implementation of AP–16.1Q and AP–16.4Q) was adequate, but found the Trend Program to be unsatisfactory. Overall, the audit team determined the corrective action process (CAP and Trend Program) to be ineffective. The

audit team recommended that the classification of CR–6711 be elevated from Level B to Level A. OQA management stated that they will process the audit team’s recommendation, and that OQA intends to conduct a formal assessment of progress in the Trend Program in approximately six months.

4.5 Potential Audit Findings

The audit team initiated Level C CRs for

- Minor procedure inadequacies
- Failure to initiate a CR from nonconformance reports (NCRs) (i.e., for nonconforming materials, parts, or components) that reference human performance issues
- Failure to perform functional evaluations for three NCRs
- Failure to cross-reference actions required from a canceled CR to another CR action
- Inadequate records package for a canceled CR

In addition, the audit team identified the following opportunities for improvement:

- The supplemental information fields in the CRs should include date information (to provide a time perspective in relation to other entries)
- Corrective action verification should include and document completed actions that did not result in individual planned actions (i.e., actions completed prior to the action planning process)
- CR classification guidelines in AP–16.1Q should indicate that adverse trends are classified as Level A rather than Level B CRs
- The Screening Classification Team should evaluate repeat issues to identify trends as part of its routine CR classification activities

5.0 NRC STAFF FINDINGS

5.1 NRC OBSERVATION SUMMARY

The observers determined that the audit team performed the audit effectively and demonstrated sound knowledge of the applicable implementing procedures and QARD requirements. However, during the conduct of the audit, the observers noted that the audit team was not evaluating the implementation of the Trend Evaluation and Reporting procedure and did not appear to be performing the actions necessary to determine the effectiveness of the corrective action process. After comments from the observers, the audit team evaluated the Trend Program and added evaluations of corrective action effectiveness reviews that had not originally been included in the audit scope.

The auditors conducted thorough interviews, challenged and questioned responses when appropriate, and effectively employed their checklists. The observers agreed with the auditors’ overall conclusions, individual findings, and opportunities for improvement.

5.2 NRC AUDIT OBSERVER INQUIRY

The observers initiated no Audit Observer Inquiries during this audit.